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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,544	12/14/2005	Breda Mary Cullen	JJM5011USPCT	6443

27777 7590 05/13/2008

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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
05/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/560,544	CULLEN ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 5 - 13, 15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5 - 13, 15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed December 13, 2007, have been fully considered but they are not deemed to be fully persuasive. The following rejections constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 13 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because of the inclusion of the phrase “at least about”. This rejection is MAINTAINED.

Applicant argues that various decisions have found similar language to be definite (see p 5 of the Response) and that the claims must be as precise as the subject matter permits and that claim 13 is not vague and indefinite.

These arguments are not found to be persuasive. When used separately, “at least” and “about” are not indefinite terms. However, when used in combination these terms are not definite. To provide a concrete example, it is unclear whether an antioxidant activity of 14.9% is within the scope of these claims. This value is about

15%, but it is not at least 15%. Therefore, the metes and bounds for the required amount of antioxidant cannot be determined and the claim is vague and indefinite.

The deletion of the phrase "as defined herein" from this claim when referring to the test used to determine the antioxidant activity has resolved the indefiniteness of this part of the claim.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1 – 6 were rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al. (EP 0 368 253). Due to the amendments of the claims to recite a wound dressing material comprising an oxidized cellulose solid bioabsorbable material, this rejection is WITHDRAWN.

Claims 7 – 13 were rejected as being unpatentable over Partain et al. in view of a secondary reference (Fowler et al., Nimrod et al. or Gibbins). These rejections are also WITHDRAWN.

Double Patenting

Applicant asserts that these rejections should be withdrawn because none of the Applications have issued as patents. However, whether or not a patent application has issued as a patent does not negate the fact that the applications have overlapping subject matter. Applicant is respectfully requested to review MPEP § 804 which explains double patenting and possible ways in which a double patenting rejection may be overcome.

5. Claims 1 – 3 and 12 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 4 and 13 of copending Application No. 11/608553 in view of Partain et al. In view of the amendments to the claims, this rejection is now made against claims 1 and 12 of the instant application. This rejection is MAINTATINED for the reasons of record set forth in the Office Action mailed October 1, 2007 and those set forth below.

As amended, the claims of the instant application recite a wound dressing material comprising oxidized cellulose as the solid bioabsorbable material. The claims of '553 recite a wound dressing composition comprising human recombinant collagen and oxidized cellulose. In view of the teachings of Partain et al. and the open language of the instant claims, the provisional rejection is maintained.

This is a provisional obviousness-type double patenting rejection.

6. Claims 8 – 10 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 13 of copending Application No. 10/579850 in view of Partain et al. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 1, 2007.

This is a provisional obviousness-type double patenting rejection.

7. Claims 8 – 10 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 – 11 of copending Application No. 10/527421 in view of Partain et al. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed October 1, 2007.

This is a provisional obviousness-type double patenting rejection.

8. Claims 1 – 3 and 12 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5 – 8 and 10 – 13 of copending Application No. 10/528262 in view of Partain et al. In view of the amendments to the claims, this rejection is now made against claims 1 and 12 of the instant application. This rejection is MAINTATINED for the reasons of record set forth in the Office Action mailed October 1, 2007 and those set forth below.

As amended, the claims of the instant application recite a wound dressing material comprising oxidized cellulose as the solid bioabsorbable material. The claims

of '262 recite a wound dressing composition comprising chitosan and oxidized cellulose. In view of the teachings of Partain et al. and the open language of the instant claims, the provisional rejection is maintained.

This is a provisional obviousness-type double patenting rejection.

New Claim Rejections - 35 USC § 103

5. Claims 1 and 4 – 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al. (EP 0 368 253) in view of Rosenthal et al. (US 5,565,210).

Partain et al. teaches delivery systems comprising aminopolysaccharides such as chitosan derivatives (col 2, ln 32 – 35) and glycosaminoglycans such as hyaluronic acid, chondroitin sulfate and heparin (col 8, ln 55 – 59). Compositions comprising chitin and chitosan are useful in accelerating the healing rate of wounds (col 8, ln 35 – 38). Additionally, this delivery system can contain antiseptic agents such as acridine dyes (col 10, ln 12). The compositions can be applied to the skin as a pre-formed film or sponge (col 4, ln 1 – 4). The compositions of Partain et al. are not explicitly disclosed as being bioabsorbable. However, the dissolution is a property of the polysaccharide used and since the polysaccharides taught are the same, the delivery systems of Partain et al. are bioabsorbable.

Partain et al. does not disclose the use of oxidized cellulose or regenerated oxidized cellulose in the delivery system.

Rosenthal et al. discloses bioabsorbable wound implant materials (col 1, ln 6 – 7). These compositions can be made from a variety of bioabsorbable materials, including polysaccharides such as collagen (col 3, ln 18 – 21), chondroitin sulfate, hyaluronic acid, heparin sulfate or oxidized regenerated cellulose (col 3, ln 26 – 30).

It would have obvious to one of ordinary skill at the time of the instant invention to prepare a composition comprising a bioabsorbable substrate with an antioxidant dyestuff as taught by Partain et al. and to use oxidized regenerated cellulose as the biabsorbable material in the wound dressing material as that ingredient is taught by Rosenthal et al. as functionally equivalent to the bioabsorbable substrates taught in Partain et al.

6. Claims 1, 7 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al. and Rosenthal et al. as applied to claims 1 and 4 – 6 above in view of Fowler et al. (US Patent 5,667,501).

As discussed above, Partain et al. and Rosenthal et al. teaches a wound dressing material comprising the bioabsorbable material of oxidized regenerated cellulose and an acridine dyes.

Partain et al. does not teach the amount of dye present or the free radical activity of the polymer.

Fowler et al. teaches wound dressings that contain chemically modified polymers. The base polymer does not possess the free radical activity but groups with the desired activity are added to the base polymer (col 2, ln 45 – 50). The free radical

activity of the polymers in the DPPH test can be in the range of about 15 – 80% (col 2, ln 24 – 25).

Acridine dyes can be oxidized and therefore act as an antioxidant. Given the effective range of free radical activity taught by Fowler et al., it would have been to obvious to one of ordinary skill in the art to add the antioxidant dyestuff at a level that resulted in an free radical activity in the effective range to the bioabsorbable wound dressing material comprised of oxidized regenerated cellulose as taught by Partain et al. and Rosenthal et al.

7. Claims 1 and 7 – 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al., Rosenthal et al. and Fowler et al. as applied to claims 1, 7 and 13 above in further view of Nimrod et al. (WO 87/05517).

As discussed above, As discussed above, Partain et al. and Rosenthal et al. teaches a wound dressing material comprising the bioabsorbable material of oxidized regenerated cellulose and an acridine dyes. In addition to antiseptic agents such as acridine dyes (col 10, ln 12 of Partain et al.), this delivery system can also contain antibiotics (col 9, ln 55 of Partain et al.). Fowler et al. teaches the desired free radical activity and therefore the amount of antioxidant present in the wound dressing.

None of the references teach the inclusion of a silver salt.

Nimrod et al. teaches heavy metal salts of hyaluronic acid, an anionic polymer where the heavy metal can be silver (p 4, ln 27). Silver ions are effective antimicrobial agents without significant side effects that are rarely associated with silver antibiotic-

resistant strains of bacteria. Silver salts are useful as topical anti-infectives or antiseptics (p 3, ln 7 – 13).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to prepare a composition comprising both a heavy metal salt of the polysaccharide and the acridine dye as all the references relate to wound dressing materials.

8. Claims 1, 6, 7, 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Partain et al., Rosenthal et al. and Fowler et al. as applied to claims 1 – 7 and 13 above in further view of Gibbins (US Patent 6,355,858 B1).

As discussed above, Partain et al., Rosenthal et al. and Fowler et al. teaches oxidized regenerated cellulose wound dressing materials comprising acridine dyes with an antioxidant activity of at least 15%.

None of the references teach that the delivery vehicle is in the form a sheet or that the material is sterile and placed in a microorganism-impermeable container.

Gibbins teaches wound dressings that administer an active agent (col 4, ln 8 – 11). Active agents can include silver salts as an anti-microbial agent (col 7, ln 2). The matrix material can be cut from a sheet and sterilized by a number of methods (col 12, ln 52 – 65).

It would have been obvious to one of ordinary skill in the art with a reasonable expectation of success to take the wound dressing composition of Partain et al. and Fowler et al., form it into a sheet, cut to the desired pattern or shape, and then sterilize

the wound dressing material as taught by Gibbins. Once sterile, it would be obvious to place the sterile material in a container or packaging to maintain the sterility of the matrix ("microorganism-impermeable container").

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW